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Title

Preventing Retained Central Venous Catheter Guidewires: A Randomized Controlled Simulation Study using a Human Factors approach

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Abbreviated Title

A novel approach to preventing retained guidewires

Conflicts of interest

Dr Young has patented and is the inventor of the Venner WireSafe™ based on the locked pack described in this paper. Dr Mariyaselvam has been selected as an NHS Innovation Accelerator Fellow and NHS Clinical Entrepreneur Fellow to support the implementation of the Venner WireSafe™. Both have ownership rights to the intellectual property and hope to be involved with supporting and advising on the

commercialization of the Venner WireSafe™ and may benefit financially alongside its clinical success, subject to future negotiation and agreement. All other authors declare no conflicts of interest.

Abstract

Background: Retained central venous catheter guidewires are never events. Currently, preventative techniques rely on clinicians remembering to remove the guidewire. However, solutions solely relying upon humans to prevent error inevitably fail. A novel locked procedure pack was designed, to contain the equipment required for completing the procedure after the guidewire should have been removed: suture, suture holder and antimicrobial dressings. The guidewire is used as a key to unlock the pack and to access the contents, thereby the clinician must remove the guidewire from the patient, in order to complete the procedure.

Methods: A randomized controlled forced-error simulation study replicated catheter insertion. We created a retained guidewire event, and then determined whether clinicians would discover it, comparing standard practice against the locked pack.

Results: Guidewires were retrieved from 2/10 (20%) standard v 10/10 (100%) locked pack, n=20, P<0.001. In the locked pack group, participants attempted to complete the procedure, however, when unable to access the contents, this prompted a search for the key (guidewire). Participants discovered the guidewire within the catheter lumen, recovered and utilized it to unlock the pack, and finished the procedure. A structured questionnaire reported that the locked pack also improved subjective safety of central venous catheter insertion and allowed easy disposal of the sharps and guidewire (10/10).

Conclusions: The locked pack is an engineered solution designed to prevent retained guidewires. Utilizing forced-error simulation testing, we have determined that the

92 locked pack is an effective preventative device, and is acceptable to clinicians for
93 improving patient safety.

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Introduction

Central venous catheters are used in healthcare for monitoring and administering medications. More than 5 million central venous catheters are placed every year in the United States (US).[1] The standard technique for central venous catheter insertion is the Seldinger method however, it is associated with guidewire retention, which can cause complications such as arrhythmia, thrombosis, cardiac perforation and tamponade.[2] Retained guidewires have an incidence of 1:3291 procedures,[3] a reported mortality of up to 20%,[2,4] and are considered a 'never event' in the US and United Kingdom.[5,6] Therefore, they are regarded as preventable errors, which should not occur.[5,6] Case reports of retained guidewire events in the literature describe reasons for the error as inattention,[7,8] distraction,[9] inexperience,[7] inadequate supervision,[7,9] high workload[9] or staff fatigue.[8] The authors conclude that guidewire retention is preventable with appropriate re-training of staff by highlighting the importance of guidewire removal,[2,10] by using a two-person approach,[10,11] by introducing a checklist,[11] by checking the trolley after the procedure,[12] by ensuring the clinician grips the proximal end of the guidewire at all times,[8] by not inserting the guidewire beyond 18cm[13] and having active senior supervision at all times with trainee doctors.[9,11] Despite these suggestions, the incidence of retained guidewires continues to rise and are reported twice a month in the NHS.[14] These measures do not reliably prevent the error, because they are reliant on the human operator remembering to perform the safety check.[15] Humans are fallible and prone to mistakes. Solutions which

rely solely on the operator preventing mistakes are unlikely to be completely effective. The transport and energy industries routinely use safety engineering to modify their equipment and design errors out of the system.[16] In healthcare, for single procedures with specific known errors, it may be possible to use safety engineering to modify the equipment, to ensure the operator conducts the procedure by the safest method. We aimed to engineer a safety solution to prevent the error of retained guidewires (appendix 1). The solution was tested in a forced-error simulation study, with operators who had no experience of the solution. The design of the simulation study was based on real never event cases reported to NHS England's national reporting database.[17] Forced-error simulation techniques are used in the transport and energy industries to test safety solutions to rare errors, such as air bags in cars or emergency switches in airline cockpits.[18,19] This technique manipulates the simulated environment to make a rare incident very common, in order to allow preventative solutions to be tested. The participant is initially 'forced' into making the error, and then it is determined whether the intervention makes the participant recognize the error and subsequently correct the mistake. For rare errors, occurring in one in several thousand procedures, forced-error simulation is a validated, safe, repeatable and inexpensive test methodology.[18,19]

The primary outcome was incidence of guidewire retention at completion of central venous catheter insertion.

Materials and Methods

Ethical approval to conduct the research was granted by the University of Cambridge. The institutional research and development review board approved the simulation study that was conducted at the Queen Elizabeth Hospital, Kings Lynn on a single day on 4th September 2015 to ensure confidentiality of study design between participants. Volunteers were requested and self-selected on a single day from the operating room, the intensive care unit and the general medical and surgical wards. All volunteers were capable of independent central venous catheter placement (n=20, none excluded) (figure 1a). Signed, informed consent was taken from all participants, who were qualified medical doctors at various degrees of seniority (foundation trainee to consultant level; equivalent to intern to attending physician in US parlance). Participants were randomized to standard practice or locked pack by sealed envelope randomization. Twenty identical envelopes were sealed with control (n=10) or intervention (n=10) indicated on paper within and shuffled into a random order. Immediately prior to a participant entering the scenario room, the data collection team (blinded to the participant's identity) opened an envelope and set up the procedure trolley appropriately.

A scenario was described to the participants using a standardized script prior to entering the room. The scenario outlined was that a colleague had been urgently called away, part way through a routine central venous catheter insertion on a clinically stable patient. Participants were asked to assess the situation, complete the procedure safely and perform any additional safety checks prior to approving the central venous catheter

for use. The simulation utilized a manikin model (Laerdal, Gatesville, USA) adapted for central venous catheter insertion and was covered with standard blue surgical drapes (Vygon, Swindon, UK) with a clear window for central venous catheter insertion. A central venous catheter (Arrow International Inc., Reading, UK) was placed in the right internal jugular vein, with the guidewire clearly visible in the transparent portion of the catheter lumen, adjacent to the luer hub (figure 1b). The guidewire was easily retrievable, if recognized, with fingertips or artery forceps, which were provided upon request. The manikin was connected to an ECG monitor, which displayed ectopic beats and an ultrasound machine was available for use if required. A trolley with the equipment required to perform central venous catheter insertion (Rocialle, South Wales, UK) was positioned to the right of the patient. Equipment was arranged depending on participant randomization to standard practice or locked pack group. An assistant was available to help the participant if required and answer questions. If participants specifically asked about the location of the guidewire, the assistant stated that they had not seen it. If asked about the ectopic beats, the assistant stated these had commenced during the procedure. In the control group, participants entered the room, assessed the situation and proceeded to secure the central venous catheter in place and apply the dressings. Upon completing the procedure to their satisfaction and safely disposing of the equipment, participants were asked whether they would perform any additional safety checks prior to using the central venous catheter. Participants randomized to the locked pack group, entered the room, assessed the situation and proceeded to secure the central venous catheter in place. The assistant did not explain how to use the locked

pack. If participants specifically asked, the assistant stated that the locked pack was a new safety initiative, but were unsure of its purpose or how to use it. Instructions on the locked pack indicated that the guidewire should be inserted and lifted to open. At the end of the procedure, participants randomized to the locked pack group were given a structured verbal questionnaire, asking their opinion of the locked pack in terms of subjective safety of procedure, convenience, sharps disposal and guidewire disposal (all categorized as better, same, or worse).

Statistical Analysis

We calculated a power of 0.87 for a statistical significance of 0.05 and for n=10 to detect a 50% absolute difference in proportions, and used a two-tailed Fisher's Exact test to analyze the data (GraphPad.com). The criterion for statistical significance was 0.05.

Results

The standard group consisted of 4 females (aged between 23-60 years), 6 males (aged between 24-60 years) of which 4 were senior and 6 were doctors in training posts. The locked pack group consisted of 3 females (aged between 25 – 40 years), 7 males (aged between 25 years to 60 years) of which 3 were senior and 7 were doctors in training posts. Use of the locked pack prevented guidewire retention at completion of central venous catheter insertion. Guidewire retention was prevented in 2/10 (20%) standard v 10/10 (100%) locked pack, n=20, $P < 0.001$. In the standard group 80% (8/10) of participants failed to recognize the guidewire in the catheter lumen. They secured the central venous catheter, applied the dressings and were satisfied that they had completed the procedure correctly. In the locked pack group, 2 participants recognized the guidewire in the lumen. Those that did not (8/10) attempted to complete the procedure. However, inability to access the equipment inside the locked pack triggered a search for the guidewire by the participant. Participants searched the trolley, floor and sharps bin before looking at the central venous catheter, and finding the guidewire within the catheter lumen. All participants in the locked pack group were able to remove the guidewire, use it to open the locking mechanism (opening procedure took <10s in all cases) and finish the procedure. The structured questionnaire of the locked pack group reported that it improved the safety and convenience of central venous catheter insertion and allowed easy disposal of the sharps and guidewire (10/10).

Discussion

A retained central venous catheter guidewire is never event, which affects patients, clinicians and hospitals. The reasons for retained guidewires are well documented in the literature and preventative approaches traditionally include appropriate re-education and re-training of staff when the error occurs and highlighting the importance of guidewire removal.[2,10] However, "re-education and training is only as good as the length of time that clinicians remember to do it"[15] therefore this solution necessitates repeated episodes of training and often a cycle of recurrent mistakes. Other suggestions are that loss of the guidewire is preventable with a two-person approach, or with a second person witnessing guidewire removal.[10,11] Requiring two individuals to perform a procedure is both time and cost ineffective, and not always possible in a busy hospital environment without frequent delays to every central line insertion. Furthermore, in terms of rare events, after thousands of procedures with no errors, this leads to creeping complacency by both individuals, with each individual relying on the other to conduct the procedure correctly and leading to unclear accountability.[12] Several reports suggest having active supervision by senior staff at all times during procedures.[9,11] However, a number of cases report guidewire retention, despite adequate senior supervision[9] and this solution does not address the cases when very experienced senior clinicians make this mistake.[9]

Another common suggestion is that guidewire retention is preventable if the clinician grips the proximal end of the guidewire at all times[8] or ensures that they do not insert the guidewire beyond 18cm.[13] However, it is difficult to always ensure that clinicians act

234 in this way, especially when the lone operator is single-handedly manipulating
235 equipment or when distractions or clinical emergencies occur.[2,16] Other suggestions
236 have included, introducing a checklist for central venous catheter insertion, requiring
237 the documentation of guidewire removal[11] or checking the trolley after the procedure.[12]
238 Similarly, these measures are reliant on the clinician remembering to perform the safety
239 step, and are prone to fail.

240 Safety and human factors principles demonstrate that sole reliance on humans to
241 prevent error inevitably fail.[16] Therefore, rather than introducing complex protocols,
242 which require the clinician to remember to perform the safety action, the best method is
243 to introduce engineered safety systems which allow the operator to perform their job
244 safely and prevent the error. Human factors engineering is used in the energy and
245 transport industries to promote safe practice by anticipating error and re-designing
246 equipment to minimize mistakes.[20] This is possible in healthcare with an understanding
247 of the procedure, operator and working environment.[21] If guidewire retention is
248 immediately recognized, the guidewire often remains within the catheter lumen.[17] At
249 this stage, retrieval is almost always possible by clamping artery forceps at the skin level
250 to the catheter and enclosed guidewire and removing enblock,[9] reversing the potential
251 of further migration and embolization. In this study, use of the locked pack prevented
252 guidewire retention when compared with standard practice. Use of the locked pack
253 forced participants to recognize guidewire retention, as they were unable to complete
254 the procedure without it, and ensured the guidewire was removed each time. The locked
255 pack was also found to be intuitive to use, as all participants, despite being naive to the

device were able to understand how to use the device. All participants took less than 10 seconds to utilize the guidewire to unlock the mechanism and access the contents. An interesting observation in the locked pack group was the participant's behavior when searching for the guidewire. Participants initially searched the trolley, floor and sharps bin, and finally looked at the central venous catheter lumen. This highlights that the error of a retained guidewire is a low possibility in the clinician's mind. Commonly proffered solutions in this context include reiteration and emphasis of the importance of guidewire removal. Forcing awareness of a rare error into the mind of the operator increases cognitive load and has the potential to detract awareness from other central venous catheter complications, such as pneumothorax, arterial puncture, dysrhythmias, air embolism.[22] The locked pack aided the participant to recognize the error at an easily correctable point during central venous catheter insertion, without adversely interfering with the procedure. In clinical practice, the locked pack would ideally be incorporated and supplied as part of the central line insertion sterile pack.

The design of the simulation study was based on real never event cases reported to NHS England's national reporting database[17] and was performed in such as way as to 'force' the error to occur within the scenario. Critics of forced-error simulation may argue that the simulation scenario was unrealistic and the locked pack should be tested replicating routine clinical practice. However, for an error that occurs in 1:3291 procedures, a power calculation (GraphPad.com) shows that a total of 12,000 participants would be required for the study if one were to test the device replicating routine clinical practice. To contextualize this, there are 13,955 Anesthetists in the UK.[23]

Replicating routine clinical practice is therefore an impractical vehicle to test a safety solution for a rare error, in a safe, repeatable and inexpensive fashion. Therefore the most cost-effective and practical approach to testing rare errors, is to evaluate the intervention in a forced-error simulation, hence the current scenario was used, which was based on real case events. The energy and transport industries are often called the high reliability industries,[24] due to their adoption of a human factors safety culture and their high safety records. In these industries, similar solutions are tested with forced-error simulation, replicating rare errors to analyze operator behavior and improve or test new safety measures.[25] For example, in the car industry, this approach has been used in airbag deployment testing. Industry standards require the replication of the driver being forced into common car crash positions in order to test the effectiveness of the safety technology, in this case air bags.[18] It is impossible to test the ability of equipment designed to improve safety during car crashes, without crashing the car. One could perform routine practice, by simply driving the car for thousands of hours and waiting for a crash to occur before determining the safety of the equipment. However this is unsafe, expensive and time inefficient. Therefore, the manufacturer forces car crash scenarios, testing the efficacy of the equipment in a repeatable forced-error simulation. Lessons from industry indicate that it is more cost effective to systematically design methods to test safety interventions, where the scenarios are designed to align the latent causes of failure, to make a rare event more common[26] – an extrapolation of Reason's Swiss Cheese Model.[27] This engineered sensitization of enhanced risk also

removes variability in operator performance and procedure context that may modulate outcome, and thus provides a more tractable context for assessing the intervention.

Despite the majority of reported retained guidewire incidents being single catheter insertions (97.5%),[17] another criticism of the locked pack may be that is does not prevent the rarer event in which two or more catheter packs are opened. This happens in two scenarios. The first of these is where there is a planned insertion of multiple central venous catheters within the same procedure, with the use of multiple kits. The second of these is the minority of cases where there has been a difficulty in catheter insertion with the first kit, and a second kit is opened. While the locked pack would not be able to assuredly prevent guidewire retention in either of these situations, they represent a small minority of reported retained guidewire incidents (2.5%)[17] and the locked pack approach could still substantially mitigate the risk of this never event in the substantial majority of cases. To circumvent this problem, one could use an equivalent number of locked packs on the sterile field, however we are in the process of exploring this area with a view to design improvements to address the problem. Concurrently, we are also exploring the expansion of the locked pack to other Seldinger techniques, which are associated with guidewire retention such as chest drain insertions.

Importantly, one must remember that while engineered solutions provide greater assurance of safety, no single intervention, on its own, represents a foolproof solution. The introduction of safety initiatives are not designed to remove the need to cognitively engage during the procedure, but to minimize error and aid the operator to

perform their job safely. If introduced clinically, we believe the locked pack will improve patient safety and protect clinicians from making this error.

Conclusion

A retained central venous catheter guidewire is a never event. Current preventative solutions are dependent on the operator remembering to remove the guidewire. Using human factors engineering principles, we have designed a safety intervention, a novel locked procedure pack which acts to ensure the operator always removes the guidewire, thereby preventing the never event. We have tested the solution with forced-error simulation testing – a novel clinical application of methodology that is validated in the high reliability industries. We believe that adoption of this technique can not only improve patient safety, but also protect clinicians from making this error.

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Appendix 1

Developing the novel procedure pack

Retained guidewires during the central venous catheter placement occur at a 'critical point' in the procedure – when the catheter is placed over the guidewire. At this point, if the clinician is inexperienced or distracted, they can forget that the guidewire has not been removed. Without realizing this, they will continue to advance the catheter, and finish the procedure by securing the catheter in place. Guidewire retention is then often discovered on or after the initial check x-ray and even at this stage migration may not have occurred and removal is often possible.[14,17]

A novel procedure pack was designed to ensure removal of the guidewire after the 'critical moment.' Normally, after the guidewire is removed from the patient and in order to complete the central venous catheter procedure, the following equipment is needed: suture, suture holder and antimicrobial dressing. We developed a locked pack with a key-lock mechanism, which contained the suture, suture holder and antimicrobial dressing (figure 2). The guidewire is used as a key. It is inserted into the lock, and remaining inside the lock, is used as a handle to open the lid of the locked pack, to allow the operator to access the suture, suture holder and antimicrobial dressing (figure 3). Therefore, the only way in which the operator can access the contents to complete the procedure is by firstly removing the guidewire from the patient after the 'critical point'. This ensures that the clinician remembers to remove the guidewire, as they are unable to complete the procedure without doing so. As an additional safety feature, a sharps sticker was placed at the base of the locked pack and instructions for use on the

underside. Once the suture, suture holder and dressings have been removed, the sharps sticker becomes visible (figure 4). The now empty locked pack becomes a convenient and safe container for collecting the sharps used during the central venous catheter insertion. The used sharps are placed inside the locked pack and the lid is securely closed, with the guidewire safely retained inside the locking mechanism (figure 4, if required, it is possible to remove the guidewire from the locked pack). The locked pack is then disposed of into the sharps bin (see Video, supplemental Digital Content 1, which illustrates the instructions for use of the novel locked pack).

Prototype Locked pack: This was a box of dimensions 3cm height x 10cm width x 20cm length (figure 2). This contained all the equipment required to complete a central venous catheter insertion procedure from the moment immediately after the guidewire should have been removed: the suture, suture holder and antimicrobial dressings. The lid was designed flush to the box and held shut with a magnet inset into the lid and a metal plate on the box. This made the lid unable to be gripped and opened. The magnet held the lid closed even if inverted and the contents shaken.

Opening mechanism: A light bulb-shaped channel within the lid accepts a guidewire as large as 10G in size. The guidewire easily passes round the channel and emerges through an identical second hole parallel to the entry hole (figure 3). After passing a guidewire this leaves two ends which forms a convenient handle. The lid is easy to open with counter-traction provided by the angular force of lifting the newly created guidewire handle.

The prototype procedure pack lid firmly closes again so that following the procedure it could be used as a point of care sharps receptacle and guidewire retainer to facilitate safe disposal (figure 4).

Figure legends

Figure 1: A) A flow diagram detailing the methodology of the simulation study. B) a blown up version of the manikin clearly displaying the guidewire within the catheter lumen, 1) shows the guidewire within the catheter lumen, 2) showing the tip of the guidewire just protruding from the brown hub, but not visible within the clear hub.

Figure 2: A prototype of the locked pack, which contains the contents required to complete a central venous catheter insertion: suture, suture holder and antimicrobial dressing. The locked pack is in the closed position and appears, as it would be introduced onto the sterile field of the central line trolley. A) the magnet in the lid and metal plate in the base, which holds the pack closed in the locked position. B) are the entry and exit channels for the guidewire, C) is the guidewire channel, through which the guidewire is inserted, D) is the hinge of the lid of the locked pack. Prototype courtesy of Venner Medical Technologies, Singapore.

Figure 3: Showing the locked pack which can only be opened with the guidewire. A1) step 1, the tip of the guidewire is inserted into entry opening of the channel. B2) step 2, the guidewire is pushed through the light bulb shaped channel until the tip emerges from the exit of the channel. B3) step 3, both of the ends of the guidewire will protrude from the channel. C4) step 4, both ends of the guidewire are gripped with fingers and it is used as a handle to open the lid of the box. D5) step 5, counter traction is applied by placing fingers placed on the bottom shelf. D6) step 6, the ends of the guidewire are used

as a handle and pulled upwards, to open the lid of the locked pack and allow the user to access the contents.

Figure 4: The locked pack becomes a convenient sharps disposal. A1) the sharps from central venous catheter insertion are placed inside the pack. B2) The lid is closed, securing the sharps inside the locked pack. B3) the guidewire remains inside the channel of the lid. The whole apparatus is then disposed of into the sharps bin.

Supplemental Digital Content

Supplemental Digital Content 1: Video which illustrates the instructions for use of the novel locked pack. mp4